

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed February 14, 2011. Claims 1-25 were pending and claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-93 were rejected in view of cited art. The same claims were also rejected under the doctrine of nonstatutory obviousness-type double patenting over generally the same art. One or more of these rejections appear to be identical or at least similar to objections that were applied and overcome previously. By the present response, independent claims 41, 72, and 86 are amended, and new claim 94 has been added. Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 are now pending.

Applicants also wish to note that the prior 35 U.S.C. § 112 written description rejection and the obviousness rejection based on U.S. Patent No. 6,108,850 to McLaughlin have been withdrawn as a result of the Pre-Appeal Panel Decision dated December 6, 2010.

Reconsideration of the application is respectfully requested in view of the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

### **B. PRIORITY CLAIM**

The present Amendment alters the priority claim by deleting any priority claim to U.S. Patent Application Serial No. 09/190,709, filed November 12, 1998. The earliest claim to priority as the priority claim has been amended is January 31, 2000. No priority is claimed to the November 12, 1998 filing. This claim to priority is actually consistent with the priority claim currently displayed in Private PAIR, which shows that the present application claims priority to just the patent and application, filed in October and January 2000, respectively.

**C. REJECTION UNDER 35 U.S.C. § 103(a)**

**I. U.S. PATENT NO. 5,851,512**

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-93 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,851,512 to Fischer.

As the Examiner is aware, Applicants performed a comparative study and found that bleaching compositions that included 0.5% potassium nitrate and 10.5% bleaching agent unexpectedly resulted in substantially lower oral sensitivity compared to compositions that included 3% potassium nitrate and either 10.5% or 15% bleaching agent. The comparative study is explained on pages 26-29 of the Application and was the subject of a previously filed declaration. Indeed, the Examiner has previously stated agreement that the comparative study shows surprising and unexpected results but has in the past argued that the claims are not commensurate in scope with the comparative study because the claims recite ranges of about 10-30% bleaching agent and about 0.01- less than 2% potassium nitrate.

If using an amount of potassium nitrate (e.g., 0.5%) within the narrowly tailored concentration range of about 0.01- less than 2% together with a commonly used amount of bleaching agent (e.g., 10%) was more effective in mitigating oral sensitivity that would otherwise be caused by the dental bleaching agent than when a larger amount of potassium nitrate was used (i.e., 3%), it may reasonably be concluded that this trend would continue when larger (e.g., up to about 30%) or smaller amounts of the dental bleaching agent are used. Similarly, because using 0.5% potassium nitrate unexpectedly resulted in reduced oral sensitivity compared to when either 3% or 0% is used, it is reasonable to conclude that amounts of potassium nitrate within narrowly tailored ranges on either side of 0.5% would also provide greater desensitization compared to either 3% or 0% potassium nitrate.

There is no rule or case law that requires applicants to only claim the specific species used in the comparative study, and the Office Action cites to no rule or case law that would require this. To the contrary, MPEP § 716.02(d) states that "the nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof". In re Kollman, 595 F.2d 48, 56 201 USPQ 193 (CCPA 1979); In re Lindner, 457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972); In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). Previously, applicants provided graphic evidence showing such a trend, and the instant claims

only claim narrowly tailored ranges that were extrapolated from the test data and are therefore commensurate in scope with the comparative test.

In an effort to further prosecution, new dependent claim 94 has been added, which is even more narrowly tailored around the concentration values of 0.5% potassium nitrate and 10.5% bleaching agent used in the comparative testing which Examiner agrees show surprising and unexpected results. Claim 94 recites concentration values of about 0.5% potassium nitrate and 10 to 15% bleaching agent. The Examiner is respectfully requested to specifically address the allowability of new claim 94, as well as dependent claim 61, which is slightly broader, yet still narrowly tailored around the concentrations indicated in the comparative study, reciting concentration values of about 0.5% potassium nitrate and 10 to about 20% bleaching agent. It is believed that these claims are certainly sufficiently narrowly tailored around the test results showing surprising and unexpected results as to be allowable.

In a similar vein, several of the narrower independent and dependent claims recite specific potassium nitrate concentrations between about 0.05 and about 1%, and that at one point, Applicant was lead to believe that such a limitation would be allowable by the Examiner. The Examiner is respectfully requested to identify which of the claims (or which possible amendments or combinations would be) are commensurate in scope with the provided evidence of surprising results so as to be allowable.

As discussed previously with the Examiner, Example 8 of U.S. Patent No. 5,851,512 discloses a densensitizing composition with 2% potassium nitrate, but which includes no peroxide bleaching agent, as U.S. Patent 5,851,512 teaches such a combination to be unstable (see column 9 lines 35-41). In an effort to advance prosecution to allowance of the claims, Applicant notes that the broadest claims have been amended to recite that the potassium nitrate is present at a concentration of less than 2%, and that the claimed composition specifically includes both the dental bleaching agent and the potassium nitrate, and separation of the bleaching agent and potassium nitrate (i.e., a two part composition) is not required. It is respectfully submitted that this is sufficient to differentiate the claimed compositions from those disclosed within U.S. Patent No. 5,851,512, particularly in light of the surprising and unexpected results associated with the limited concentration of potassium nitrate.

## **II. U.S. PATENT NO. 5,985,249**

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-93 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,985,249 to Fischer.

U.S. Patent 5,985,249 to Fischer was filed October 14, 1997 and issued November 16, 1999. The present application was filed November 10, 2000, and claims priority to application Serial No. 09/494,113 which was filed January 31, 2000, which supports the presently presented claims. The sole inventor of U.S. Patent No. 5,985,249 is Dan E. Fischer, one of the two inventors of the present application. Based on these dates, and the fact that U.S. Patent No. 5,985,249 is not “by another”, U.S. Patent No. 5,985,249 cannot qualify as prior art under any section of 102.

Moreover, the comparative study described in the Application objectively indicates that the invention disclosed in the parent application filed January 31, 2000 was reduced to practice before November 16, 1999, which is both the issue date and publication date of the ‘249 patent. According to the present Application, the comparative study administered a dental bleaching and desensitizing composition within the scope of the claimed to patients over a period of 216 days, which is approximately 7 months. That would place the date when the invention was reduced to practice to at least as early as June 1999, which is before the issue (publication) date of the ‘249 patent. Because the Application filed January 31, 2000 was filed together with a declaration signed by both inventors, the declaration filed with the Application functions as a Rule 131 declaration for purposes of establishing an earlier invention date. As such, the ‘249 patent cannot qualify as prior art under 35 U.S.C. § 102(a) because it was not “described in a printed publication . . . before the invention thereof by the applicant” as required by 35 U.S.C. § 102(a). Therefore, the ‘249 patent is objectively only prior art, if at all, to the claimed invention under 35 U.S.C. § 102(e). Even if U.S. Patent No. 5,985,249 could qualify under 102(e) (if it were “by another”), 35 U.S.C. § 103(c)(1) precludes its application in an obviousness rejection.

## **III. U.S. PATENT NO. 6,306,370**

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-93 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,306,370 to Jensen et al.

U.S. Patent 6,306,370 to Jensen et al. was filed November 12, 1998 and issued October 23, 2001. The present application was filed November 10, 2000, and claims priority to application Serial No. 09/494,113 which was filed January 31, 2000, which supports the presently presented claims. The inventors of U.S. Patent No. 6,306,370 are Steven D. Jensen and

Dan E. Fischer, the same two inventors of the present application. Based on these dates, and the fact that U.S. Patent No. 6,306,370 is not “by another”, U.S. Patent No. 6,306,370 to Jensen et al. cannot qualify as prior art under any section of 102. In addition, even if U.S. Patent No. 6,306,370 could qualify under 102(e) (if it were “by another”), 35 U.S.C. § 103(c)(1) precludes its application in an obviousness rejection.

**IV. U.S. PATENT NO. 6,309,625**

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-93 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,309,625 to Jensen et al.

U.S. Patent 6,309,625 to Jensen et al. was filed November 12, 1998 and issued October 30, 2001. The present application was filed November 10, 2000, and claims priority to application Serial No. 09/494,113 which was filed January 31, 2000, which supports the presently presented claims. The inventors of U.S. Patent No. 6,306,370 are Steven D. Jensen and Dan E. Fischer, the same two inventors of the present application. Based on these dates, and the fact that U.S. Patent No. 6,309,625 is not “by another”, U.S. Patent No. 6,309,625 to Jensen et al. cannot qualify as prior art under any section of 102. In addition, even if U.S. Patent No. 6,309,625 could qualify under 102(e) (if it were “by another”), 35 U.S.C. § 103(c)(1) precludes its application in an obviousness rejection.

**V. U.S. PATENT NO. 6,368,576**

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-93 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,368,576 to Jensen et al.

U.S. Patent 6,368,576 to Jensen et al. was filed October 23, 2000 and issued April 9, 2002. The present application was filed November 10, 2000, and claims priority to application Serial No. 09/494,113 which was filed January 31, 2000, which supports the presently presented claims. The inventors of U.S. Patent No. 6,368,576 are Steven D. Jensen and Dan E. Fischer, the same two inventors of the present application. Based on these dates, and the fact that U.S. Patent No. 6,368,576 is not “by another”, U.S. Patent No. 6,368,576 to Jensen et al. cannot qualify as prior art under any section of 102. In addition, even if U.S. Patent No. 6,368,576 could qualify under 102(e) (if it were “by another”), 35 U.S.C. § 103(c)(1) precludes its application in an obviousness rejection.

**D. OBVIOUSNESS TYPE DOUBLE PATENTING REJECTION**

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-93 were also rejected based on obviousness type double patenting over various claims of U.S. Patent No. 5,851,512; U.S. Patent No. 5,368,576; U.S. Patent No. 6,309,625; and U.S. Patent No. 6,306,370.

None of the claims of any of these patents claim the specific recited ranges of 0.01 to less than 2% potassium nitrate, particularly the 0.5% concentration for which the testing shows surprising and unexpected results. For example, the claims of these various patents recite:

U.S. Patent No. 5,851,512 “about 0.1 to about 10%” (claim 4)

U.S. Patent No. 5,851,512 “about 1 to about 7%” (claim 5)

U.S. Patent No. 6,368,576 “up to about 10%” (claim 10)

U.S. Patent No. 6,309,625 “about 0.1 to about 50%” (claim 2)

U.S. Patent No. 6,306,370 “at least about 0.1%” (claim 1)

U.S. Patent No. 6,306,370 “about 1 to about 7%” (claim 2)

U.S. Patent No. 6,306,370 “about 0.1 to about 10%” (claims 14 & 16)

The disclosure of such claims is generally no better for supporting an obviousness-type double patenting rejection in light of the demonstrated surprising and unexpected results than the disclosure described above relative to the obviousness rejection over U.S. Patent No. 5,851,512. As explained above, it is further believed that the scope of the present claims, particularly dependent claims 94 and 61 is commensurate in scope with the comparative study and thus allowable over the cited art.

**E. CONCLUSION**

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

In particular, if the Examiner is not satisfied that the scope of the present claims is commensurate in scope with the provided evidence of surprising/unexpected results, it would be greatly appreciated if the Examiner would let applicant know what additional concentrations of potassium nitrate and bleaching agent could be tested to provide further testing evidence that would satisfy the Examiner.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and

reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 16th day of May 2011.

Respectfully submitted,

/Matthew D. Todd 57,928/

MATTHEW D. TODD  
Registration No. 57,928  
WORKMAN NYDEGGER  
Attorney for Applicant  
Customer No. 022913

MDT:JMG:cs  
3321988\_1.DOC